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recommendations to the Consensus Conference-derived guidelines.**

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Fourteen years of evolution of ESMO Guidelines: from the minimum recommendations to the Consensus Conference-derived guidelines

introduction

During the last two decades various Clinical Practice Guidelines (CPGs) have been developed by professional associations, institutions or medical societies at an international, national or regional level.

CPGs are defined as ‘systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances’ [1]. CPGs are based on the evidence-based medicine system and are a tool for transferring evidence from clinical research into practice and for influencing practitioner’s attitude [2].

As a matter of fact, CPGs are intended: (i) to assist practitioners in appropriate clinical decision making; (ii) to improve quality of healthcare and outcomes for patients; and (iii) to influence national policies for efficient allocation of resources and for better delivery systems [3]. As Eisenberg and Power pointed out, CPGs are intended to provide the right care, at the right time, for the right person and in the right way [4].

The development process of CPGs is not homogeneous among the internationally available guidelines. The differences are mainly related to several methodological issues, such as multidisciplinary, production process, etc. Not all CPGs are produced through a systematic review of evidence, a process that consists of (i) formulation of a clinical question/problem; (ii) identification of relevant papers by support staff and an expert taskforce; (iii) tabulation and synthesis of evidence by methodological experts; and (iv) process of CPGs, drafting by the experts. On the other hand, some CPGs are also developed through a narrative literature search.

Heterogeneity in the development of CPGs is a vital issue. In a recent report, nine well-known CPGs (ASCO, ESMO, NICE, SIGH, START, NHMRC, NCI, NCCN and CCO) and three representative tumors (advanced breast, lung and colon cancer) were selected and scrutinized. Results have shown that a diverse heterogeneity in development, structure, target user and endpoints was prominent among them [5].

CPGs should be properly and effectively implemented and disseminated in order to be adequately incorporated into daily clinical practice. This can be achieved by: (i) direct mailing; (ii) publication in journals or newsletters; (iii) organization or sponsoring of scientific events; (iv) training by opinion leaders;

(v) publicizing to patients or the public; and (vi) integration in recertification or licensing examinations.

Assessment of the quality of the process of development and reporting of CPGs is of paramount importance taking into account their benefits, harm, costs and practicalities. An example is the AGREE Instrument (Appraisal of Guidelines Research and Evaluation) that was established in 1998. In addition, due to both cultural and organizational differences that could exist among countries, a ‘trans-contextual adaptation’ strategy has been suggested by the ADAPTE framework [6].

historical development of ESMO CPGs

1998

The original idea for the creation of the ESMO Clinical Guidelines came from Professor Heine H. Hansen via the Central European Task Force in 1998. In particular, he visualized the need for clinical recommendations that might be more practical in daily use. This was supported at a meeting of the ESMO national representatives, who felt that the development of guidelines would contribute to the standing of medical oncology in Europe.

1999

Thus, in 1999, the ESMO Guidelines Task Force was constituted. Initially, the group began with a chairman (R. Stahel, Switzerland), a central coordinator (L. Jost, Switzerland), an ESMO officer (M. C. Reinhart) and five members (J. Herrstedt, Denmark; O. Klocke, Germany; N. Pavlidis, Greece; G. Purkalne, Latvia; and S. Jelic, Yugoslavia). During the next 5 years more members joined the task force (J. Berg, Sweden; R. Greil, Austria; V. Kataja, Finland; and J. Oliveira, Portugal).

2006

Since 1 January 2006, the Guidelines Task Force has been an independent group—the ESMO Guidelines Working Group (GLWG)—under the new ESMO Education Committee structure. It consists of: (i) an Editorial Board with a chairman (N. Pavlidis, Greece), three members (R. Stahel, Switzerland; H. Hansen, Denmark; and S. Jelic, Serbia), an *Annals of Oncology* executive (L. Rowett, UK) and an ESMO Coordinator (P. Minotti); and (ii) the seven Subject Editors responsible for the topics, the authors, the revision of the manuscripts and the presentation and discussion of final drafts with the editorial board (M. Castiglione, Switzerland; J. Oliveira, Portugal;

E. Felip, Spain; V. Kataja, Finland; M. Dreyling, Germany; L. Jost, Switzerland; and F. Roila, Italy).

2008

In 2008 the GLWG made some changes as follows: (i) an Editorial Board with a Chairman (N. Pavlidis, Greece), two members (R. Stahel, Switzerland; and H. Hansen, Denmark), an *Annals of Oncology* executive (L. Rowett, UK) and an ESMO Coordinator (R. Vecchi) and (ii) nine Subject Editors: M. Castiglione, Switzerland for breast and gynecological cancer; M. Dreyling, Germany for hematological malignancies; E. Felip, Spain for lung and head/neck cancer; P. Casali, Italy for sarcomas; V. Kataja, Finland for genitourinary cancer; A. Cervantes, Spain for gastrointestinal cancer; F. Roila, Italy for supportive care; S. Jelic, Serbia for liver, pancreatic cancer and neuroendocrine tumors; and G. Pentheroudakis, Greece for rare tumors.

2009

In 2009 F. Cardoso (Lisbon, Portugal) was appointed as the Subject Editor for breast cancer.

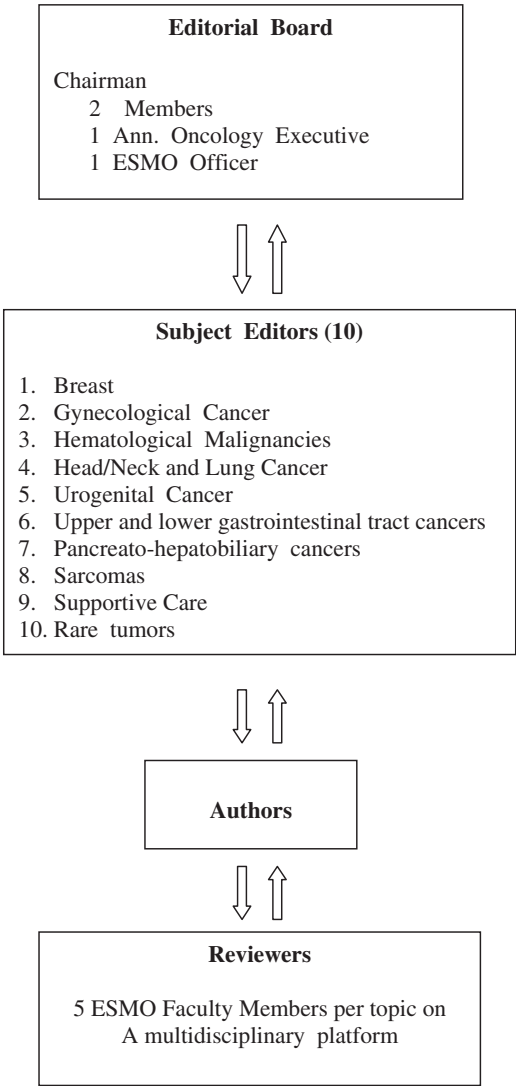


Figure 1. The structure of the EMSO Guidelines Working Group.

2011

In 2011 the Chairmanship has changed. Andres Cervantes became the Chairman of the ESMO GLWG, and N. Pavlidis became the Co-Chairman. In addition, C. Sessa (Bellinzona, Switzerland) for gynecological cancer and C. Bramley as the ESMO Guidelines and Publishing Manager.

the structure and function of the ESMO GLWG through the years

The structure of the GLWG consists of: (i) the Editorial Board; (ii) the Subject Editors; (iii) the authors; and (iv) the reviewers (five reviewers for each CPG). Both authors and reviewers are on a multidisciplinary platform and should all be ESMO Faculty members (Figure 1). The process of ESMO CPG development is demonstrated in Table 1. Nearly 14 years after the inception of the ESMO Guidelines Task Force, 54 clinical guidelines (GLs) were freely available on the ESMO website and in *Annals of Oncology*.

The initial vision of ESMO GLs was not to compete with other national or international GLs, but to be complementary recommendations to other existing guidelines and to continue to be used in day-to-day practice; in other words, ESMO GLs were based on a philosophy of providing basic and practical information to oncologists and protecting them from ‘what and how not to do things’. Therefore, ESMO GLs were at that time called ‘ESMO Minimum Clinical Recommendations’ and included GLs: (i) of a short size (1–3 pages); (ii) annually published in *Annals of Oncology* and on the ESMO website; (iii) produced by and dedicated to medical oncologists; and (iv) covering most tumor types.

Since 2006 ESMO decided to expand the size of GLs and to call them simply ‘ESMO Clinical Recommendations’. In 2007 ESMO introduced Consensus Conferences to address

Table 1. ESMO Guidelines development process

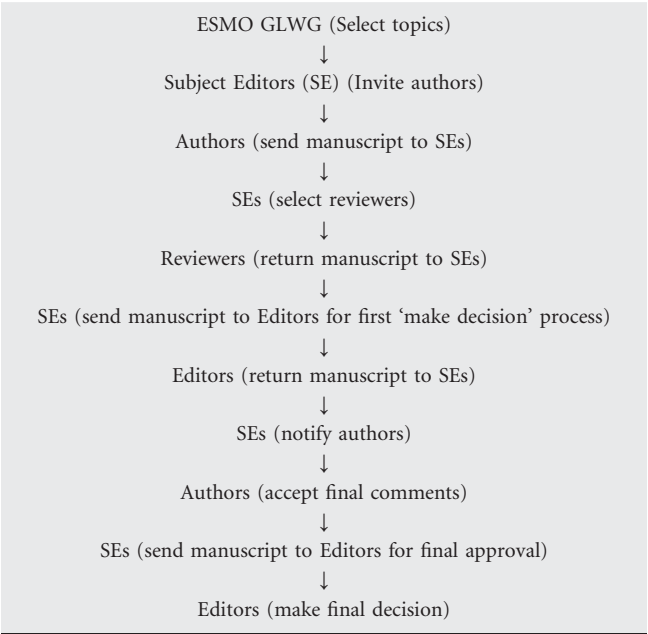


Table 2. Consensus meeting-derived ESMO CPGs

Date	Event	Venue	Funded by
October 2007	Soft tissue sarcomas and GIST	Lugano, Switzerland	Conticanet
May 2008	Testicular cancer	Munich, Germany	ESMO (EIS)
May 2009	Communication skills	Kappel am Albis, Switzerland	Swiss Cancer League
June 2009	Antiemetics	Perugia, Italy	MASCC/ESMO
November 2009	Sarcomas (STS)	Lugano, Switzerland	Conticanet
November 2009	Sarcomas (bone)	Lugano, Switzerland	Eurobonet
May 2010	Lung cancer	Lugano, Switzerland	ESMO, San Salvatore Foundation
September 2010	Colorectal cancer	Lugano, Switzerland	ESMO
June 2011	Malignant lymphoma	Lugano, Switzerland	ESMO

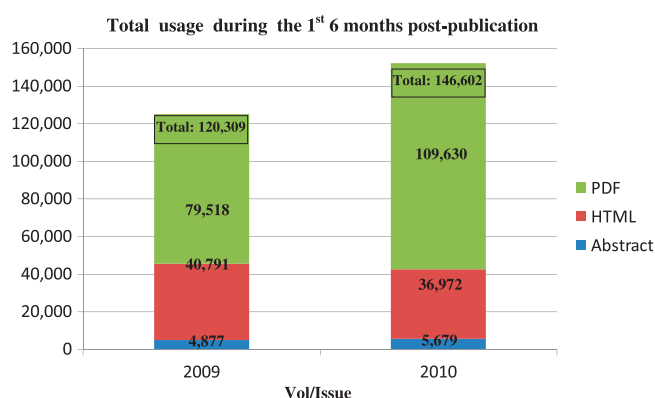
Table 3. ESMO Guidelines evolution (1998–2011)

Year	Name
1998	ESMO Minimum Clinical Recommendations
2006	ESMO Clinical Recommendations
2010	ESMO Clinical Practice Guidelines

Table 4. Universal geographical breakdown of usage (2008–2010)

Country	Total usage	%
USA	103 870	13
Italy	61 955	8
Switzerland	47 631	6
Germany	47 073	6
UK	40 696	5
Spain	35 863	4
India	29 056	4
Mexico	25 987	3
China	25 924	3
France	22 877	3
Brazil	21 932	3
Canada	20 115	2
Portugal	17 530	2
Egypt	15 541	2
Turkey	15 338	2
Japan	14 709	2
Australia	14 692	2
Romania	14 156	2
Others	232 181	28
Total	807 137	100

preselected questions on specific tumor types. The objective of these conferences is to address difficult issues using a much wider input from the oncology community by utilizing 30–40 experts. Up to now eight Consensus Conferences have taken place in various European cities (Table 2). Recently, it has also been proposed that ESMO GLs will be called ‘ESMO Clinical Practice Guidelines (CPGs)’ and all GLs will be available on the ESMO website and only the updated ESMO CPGs will be published annually in *Annals of Oncology* (Table 3). ESMO

**Figure 2.** Guidelines downloads overview (2009–2010). Total usage during the first 6 months post-publication.**Table 5.** Geographical breakdown of usage by continent (2008–2010)

Continent	Total usage	%
Europe	388 047	48
America		
North	123 985	15.5
South	55 600	7.0
Central	32 696	4.0
Asia	146 187	18.0
Africa	26 336	3.5
Australasia	16 902	2.0
Japan	14 713	1.8
Unknown	2671	0.3
Total	807 137	100

Consensus Conference-derived CPGs will also appear in *Annals of Oncology* [7–10].

Based on the lessons learned from the first Consensus Conferences, a detailed Standard Operating Procedures platform has been developed and will be implemented from 2011 onwards.

implementation of ESMO CPGs

Successful establishment of guidelines requires both adequate implementation and sufficient dissemination. Effective

implementation of CPGs facilitates knowledge uptake and more efficient patient-focused care.

The targeted health professionals for ESMO CPGs are mainly medical oncologists. The two methodological tools used to implement ESMO CPGs are the availability of CPGs in *Annals of Oncology* and the ESMO website, and the questionnaire administered (by a electronic answering system) to all attendees of the ESMO Guidelines Interactive Sessions held at every ESMO Congress. From 2005 and up to 2010 all ESMO CPGs were published annually in the *Annals of Oncology*, but they also appeared on the ESMO website. From 2011 onwards, *Annals of Oncology* will only publish the updated CPGs and the Consensus Conference-derived CPGs, while the ESMO website will host all available ESMO CPGs.

The number of downloads from data extracted from the Oxford Journals usage statistics through the years showed an exponential increase (Figure 2). The five most downloaded CPGs in 2008–2010 were breast cancer, non-small cell lung cancer, gastric cancer, epithelial ovarian cancer and colon cancer. An analysis of the geographical distribution of usage of CPGs published in Supplements of the *Annals of Oncology* from 2008 to 2010 (volume 19/suppl 2, volume 20/suppl 4, volume 21/suppl 5) is also available.

Universally the three most highly ranked countries are the USA, Italy and Switzerland. Geographical breakdown by continent showed that Europe is by far the most highly ranked continent accounting for almost the half of the downloads (Table 5). It is also interesting to point out that the total usage in North America is mostly attributed to the USA (84%) and only 16% to Canada. Concerning the European geographical distribution, Italy, Switzerland and Germany are the three nations with the highest percentage usage (Table 6).

Another tool used to evaluate the spectrum of implementation was a survey/questionnaire given during the ESMO Congresses (Table 7). The first three questions, asked at the onset, were related to audience exposure to ESMO clinical recommendations, while the seven questions asked at the end of the session were taken from the survey of Tunis *et al.* [11]. This questionnaire was prepared to assess the familiarity, confidence and attitudes relating to ESMO CPGs. More than 80% of the responders feel that ESMO CPGs are helpful for their daily practice, 85% believe that they are also a good educational tool, and 95% think that they are intended to improve patients' quality of care.

dissemination of ESMO CPGs

During the last several years ESMO CPGs have been disseminated using different methodological tools. The first tool is the translation of ESMO CPGs into various languages. Up to now they have been translated into 13 languages (Bulgarian, Chinese, French, German, Greek, Italian, Japanese, Latvian, Polish, Portuguese, Romanian, Russian and Spanish).

The second tool is the organization of the ESMO interactive sessions during the ESMO Congresses. In these 2 h interactive events 2–3 cases on various tumors or other oncology topics are presented by a young medical oncologist and discussed by an expert European oncologist based on the ESMO CPGs. Each case is followed by three multiple-choice questions which should first be answered by the audience through an electronic

Table 6. Geographical breakdown of usage in Europe (2008–2010)

Country	Total usage	%
Italy	61 955	16
Switzerland	47 631	12
Germany	47 073	12
UK	40 696	10
Spain	35 863	9
France	22 877	6
Portugal	17 530	5
Romania	14 156	4
Greece	10 499	3
Poland	10 284	3
Belgium	9785	3
The Netherlands	7503	2
Others (35 countries)	62 195	16
Total	388 047	100

Table 7. Audience questionnaire administered during the ESMO Congresses

Question	Response
1. How many time have you attended the ESMO CR sessions during ESMO congress (2000–2006)?	Once Twice Three times Four times
2. Within the last year how many times have you consulted the ESMO CRs?	Not at all Once <10 times >10 times
3. What is your preferred access to ESMO CRs?	<i>Annals of Oncology</i> ESMO website
4. Do you think ESMO CRs are helpful source of advice?	Yes No Don't know/no answer
5. Do you think ESMO CRs are good educational tools?	Yes No Don't know/no answer
6. Do you think ESMO CRs are intended to improve quality of care?	Yes No Don't know/no answer
7. Do you think ESMO CRs are intended to cut healthcare are costs?	Yes No Don't know/no answer
8. Do you think ESMO CRs will increase litigation or disciplinary action?	Yes No Don't know/no answer
9. Do you think ESMO CRs reduce physicians' autonomy and are oversimplified or 'cookbook' medicine?	Yes No Don't know/no answer
10. Do you think ESMO CRs are impractical and too rigid to apply to individual patients?	Yes No Don't know/no answer

CRs, clinical recommendations.

Table 8. ESMO Interactive Guidelines Sessions^a

Date and place of Congress	Topics discussed	Average score
2000, Hamburg	Colon Cancer	3.78
	NSCLC	
	Testicular Cancer	
2002, Nice	Cancer of Unknown Primary	4.05
	Ovarian Cancer	
	Prostate Cancer	
2004, Vienna	Breast Cancer (metastatic)	4.07
	Follicular Lymphoma	
	Rectal Cancer	
2006, Istanbul	Breast Cancer (adjuvant)	4.24
	NSCLC	
	Hodgkin's Lymphoma	
2008, Stockholm	Thrombosis and Cancer	4.48
	Pregnancy and Cancer	
	Gastric Cancer	
2009, Berlin	Cancer Pain	NA ^b
	Head and Neck Cancer	
	Renal Cell Cancer	
2010, Milan	Breast Cancer (triple negative)	4.18
	GIST	
	Pancreatic Cancer	
2011, Stockholm (to be held)	Colorectal Cancer	–
	Melanoma	
	Bladder Cancer	

^aOn a scale of 1–5.^bNA, not available.

voting system. All these sessions are well attended and it is worth mentioning that at the 35th ESMO Congress in Milan in 2010, the audience had increased up to 3200 attendees (Table 8).

The third tool is the presentation of ESMO CPGs by members of the GLWG in Congresses Symposia or other scientific events both in and outside Europe.

The last tool of dissemination of ESMO CPGs is the publication of editorials or articles in oncology journals. The aims are to increase the awareness of the European and international oncological societies about the availability, the quality and the utility of ESMO CPGs.

future developments

ESMO is introducing new ideas on CPG implementation and dissemination by producing pocket-sized booklets and mobile apps. Pocket-sized booklets will present the key information from CPG/Consensus manuscripts in a quick references format including treatment algorithms and all recommendations.

Mobile apps will present the information in pocket versions in SmartPhone and other app formats for use on mobile devices.

In addition, ESMO is aiming to produce CPG slide-sets for use by ESMO members as a teaching resource. Good clinical guidelines can have a deep impact on the quality of cancer care in a community. Moreover, if the recommendations provided are well implemented, this may eventually have a potential benefit in cancer outcomes. For this reason, ESMO is committed to produce high quality, evidence-based guidelines to offer a useful tool to the whole oncology community. Our aim is to help in keeping clinical practice within the current understanding and best science in a multidisciplinary setting. To provide such an instrument, a tremendous effort has to be made and a long, controlled process has to be organized every year with the cooperation of authors, reviewers, Subject Editors and ESMO officers. The final product of this cooperative undertaking has to benefit not only oncologists, helping them in optimal clinical practice, but also patients, giving them the opportunity for the best possible outcomes.

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